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10/659,862	09/11/2003	Wael R. Joseph	19378C (27839-139)	5051
45736 7590 12/30/2009 Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP ONE METROPOLITAN SQUARE SUITE 2600 ST. LOUIS, MO 63102			EXAMINER AHMED, HASAN SYED	
			ART UNIT 1615	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com



### DETAILED ACTION

- Receipt is acknowledged of applicants' IDS filed on 4 March 2009 and remarks filed on 3 September 2009.
- Applicant's remarks filed on 3 September 2009 regarding the provisional obviousness-type double patenting rejection are persuasive.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-14, 16-18, and 20-30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Klofta, *et. al.* (U.S. Patent No. 6,238,682) in view of Krzysik, *et. al.* (U.S. Patent No. 6,440,437), further in view of Bartels (U.S. Application No. 2003/0157195).

Klofta, *et. al.* teach a tissue product (see claim 1). The tissue product is comprised of:

- the emollient (fatty acid) of instant claim 1 (see abstract);
- the humectant (polyols) of instant claim 1 (see col. 25, line 16);
- the immobilizing agent (fatty alcohols) of instant claim 1 (see col. 24, lines 4-14);
- the compatibilizing (propylene glycol) agent of instant claim 1 (see col. 17, line 28);
- the fatty acids of instant claim 2 (see abstract);

Art Unit: 1615

- the dimethicone of instant claim 3 (see col. 20, line 18);
- the glycerin of instant claims 5-7 (see col. 17, line 21);
- the polyethylene glycol of instant claims 9 and 10 (see col. 17, lines 20-42);
- the stearyl alcohol, of instant claim 11 (see col. 24, line 11);
- the propylene glycol of instant claim 12 (see col. 17, line 22);
- the dispersing agent of instant claim 13 (see col. 22, line 24);
- the polydimethylsiloxanes of instant claim 14 (see col. 22, line 24); and
- the surfactant of instant claim 25 (see col. 5, line 17).

Klofta, *et. al.* explain that combining the disclosed ingredients into one tissue product is beneficial because they impart, "...a soft and lubricious feel..." See col. 4, line 41.

Klofta, *et. al.* teach: (1) about 5% to about 50% emollient (see col. 19, lines 25 and 26); (2) about 5% to about 60% humectant (see col. 17, line 42); (3) about 5% to about 60% immobilizing agent (see col. 27, line 15); and (4) about 5% to about 50% compatibilizing agent (see col. 19, lines 25 and 26).

Although Klofta, *et. al.* do not explicitly teach all the percentages recited in instant claims 1, 4, and 8, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

Art Unit: 1615

concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

The Klofta, *et. al.* reference is silent with respect to the (1) phase temperatures of instant claims 1 and 28-30; (2) melting point of instant claim 26; (3) and penetration hardness of instant claim 27. Applicants teach concentration ranges of emollient, humectant, immobilizing agent, and compatibilizing agent that overlap with the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, and a compatibilizing agent into a tissue product, as taught by Klofta, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into a tissue product for the beneficial effect of a soft and lubricious feel, as explained by Klofta, *et. al.*

The Klofta, *et. al.* reference differs from the instant application in that it does not teach the skin barrier of instant claims 15-17, the antioxidant of instant claims 18-20, and the sterol of instant claims 21 and 22.

Krzysik, *et. al.* teach a wipe (see abstract) comprising:

- the about 0.1% to about 30% skin barrier enhancing agent of instant claim 1 (see col. 4, line 9);
- the oil of instant claim 16 (see col. 4, line 2);
- the avocado oil of instant claim 17 (see col. 4, line 2);
- 0.3% antioxidant (within the range of instant claim 18; see col. 17, Formulas 1-7);
- the about 0.1% to about 10% sterol of instant claim 21 (see col. 7, line 56); and
- the cholesterol of instant claim 22 (see col. 4, line 4).

Krzysik, *et. al.* explain that combining the disclosed ingredients into one wipe is beneficial because they, "...help maintain skin barrier function..." See col. 2, lines 64-65.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, a compatibilizing agent, a skin barrier enhancing agent, an antioxidant, and a sterol into a tissue product, as taught by Klofta, *et. al.* in view of Krzysik, *et. al.*. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into a tissue product for the beneficial effect of a soft and lubricious feel, as explained by Klofta, *et. al.* and to help maintain skin barrier function, as explained by Krzysik, *et. al.*

The Klofta, *et. al.* reference differs from the instant application in that it does not teach the butylated hydroxytoluene of instant claims 1 and 20.

Bartels teaches a diaper composition (see abstract) comprising butylated hydroxytoluene (see examples 1 and 2).

Bartels explains that the disclosed composition is beneficial in that it can provide relief from the symptoms of diaper rash or skin irritations caused by acidic secretions resulting from teething, antibiotic dosages, bacterial infections or an acidic diet. See paragraph 0014.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, a compatibilizing agent, a skin barrier enhancing agent, an antioxidant such as butylated hydroxytoluene, and a sterol into a tissue product, as taught by Klofta, *et. al.* in view of Krzysik, *et. al.*, further in view of Bartels. One of ordinary skill in the art at the time the invention was made would have been motivated to add butylated hydroxytoluene to a tissue product to prevent skin irritation, as explained by Bartels.

\*

2. Claims 1, 23, and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Klofta, *et. al.* (U.S. Patent No. 6,238,682) in view of Krzysik, *et. al.* (U.S. Patent No. 6,440,437), further in view of Bartels (U.S. Application No. 2003/0157195), further in view of Bowser, *et. al.* (U.S. Patent No. 5,342,976).

Klofta, *et. al.* teach a tissue product (see above).

Krzysik, *et. al.* teach a wipe (see above).

Bartels teaches a wipe (see above).

The Klofta, *et. al.*, Krzysik, *et. al.*, and Bartels references differ from the instant application in that they do not teach the ceramide and glucosylceramide of instant claims 23 and 24.

Bowser, *et. al.* teach a skin composition that may be used in a tissue product, such as a tissue wipe (see col. 16, line 44).

The disclosed composition contains the ceramide and glucosylceramide of instant claims 23 and 24 (see col. 1, line 67).

Bowser, *et. al.* explain that a ceramide, such as glucosylceramide, is beneficial in a skin composition because, "...when applied topically to the skin, bring(s) about a marked improvement in skin condition, by enhancing skin barrier function." See col. 2, lines 7-9.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a ceramide, such as glucosylceramide to a tissue product, as taught by Klofta, *et. al.* in view of Bowser, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to this ingredient into a tissue product for the beneficial effect of enhancing skin barrier function, as explained by Bowser, *et. al.*

\* \* \* \* \*

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory



Art Unit: 1615

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14, 16-18, and 20-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-61 of copending Application No. 10/659,969 ('969). Although the conflicting claims are not identical, they are not patentably distinct from each other because '969 claims an absorbent product comprising a moisturizing and lubricating composition comprising an emollient, a humectant, an immobilizing agent, and a compatibilizing agent. See claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed on 3 September 2009 have been fully considered but they are not persuasive.

Applicant argues that there is no reason or motivation to combine the anhydrous lotion of Klofta with Krzysik and the anhydrous formulation of Bartels and Bowser. See remarks, pages 9-10 and 13-15.

The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Examiner respectfully submits that Klofta, Krzysik, Bartels and Bowser all involve tissue products. Krzysik was invoked for the teaching of petrolatum or mineral oil, antioxidants, and sterols in tissue products while Bartels was invoked for the teaching of butylated hydroxytoluene and Bowser was invoked for the teaching of ceramide in tissue products. The use of these ingredients in tissue products would have suggested to a person of ordinary skill in the art that they may be added to the tissue product of Klofta with beneficial effects. Neither Klofta, Krzysik, Bartels, nor Bowser suggest that a water content of 5-15% will adversely affect the functionality of petrolatum, mineral oil, antioxidants, sterols, or ceramide in a tissue product. As such, examiner respectfully submits that the three references are properly combined.

Applicant argues that Bartels teaches away from a combination of Klofta with Krzysik because Krzysik focuses on a product that helps maintain skin barrier function

Art Unit: 1615

in a diapered environment while Bartels mentions that the disclosed invention does not purport or attempt to be a barrier cream. See remarks, pages 10-11

As indicated above, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Examiner respectfully submits that Bartels teaches a diaper composition (see above); as such it is in the same field of endeavor as Klofta and Krzysik. Bartels was invoked only for the teaching of butylated hydroxytoluene. As such, examiner respectfully submits that the references were properly combined.

\* \* \* \* \*

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1615

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1615

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Application/Control Number: 10/659,862  
Art Unit: 1615

Page 12